formulary listing recommendations to publicly funded drug plans. This study aims to determine the implications of implementing CDR recommendations. **METHODS:** CDR reviews from December 2010 to December 2012, for which an economic evaluation was submitted by the manufacturer, were assessed. A framework was developed where templates were created in Microsoft Excel for each drug submission to consider two scenarios: an uptake scenario (CDR recommendation implemented), and a counterfactual scenario (CDR recommendation not implemented). Drug costs and quality adjusted life years (if applicable) for both scenarios were determined at the population level using patient numbers reported in the manufacturer's budget impact analyses. The incremental net benefit was calculated, based on a willingness-to-pay of $50,000. In addition, sensitivity analyses were conducted to consider variation around the counterfactual scenario. **RESULTS:** Based on the results for the 55 drugs for which cost-utility or a cost-minimization analysis was submitted, the total incremental net benefit of implementing a CDR recommendation was calculated to be over 1 billion dollars over a 1-year time frame for participating provincial drug plans. Detailed sensitivity analysis explored the uncertainty around these estimates. **CONCLUSIONS:** Overall, the 10 drug plans included for this analysis would realize significant benefit by implementing CDR recommendations. Based on this research, a framework to assess the impact of CDR recommendations is being developed. Next steps include, consideration of disease specific estimates of net benefit and the inclusion of all participating drug plans to provide broader implications of overall CDR impact in Canada.

HEALTH TECHNOLOGY ASSESSMENT STUDIES

HT1
RECENT HEALTH TECHNOLOGY ASSESSMENT DECISIONS ACROSS THE GLOBE: A FOCUS ON ONCOLOGY

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OBJECTIVES: Due to a substantial oncology burden across the globe, there is an increasing need for innovative, more effective oncology treatments. Although the decision-making process differs among nations, health technology assessments (HTAs) aim to produce policies that achieve optimal value while improving patient care and health outcomes. The objective of this analysis was to evaluate recent patterns in oncology-based HTA decisions in selected countries. **METHODS:** HTA surveillance was conducted for Australia, Canada, France, Germany, and the United Kingdom (UK) from January 1, 2012 to August 31, 2013 (19 months). Oncology-based HTAs were evaluated by therapeutic area, decision, and rationale for the decision. Decisions were categorized as favorable, unfavorable, mixed (ie, both favorable and unfavorable), and neutral (ie, deferral). **RESULTS:** 67 oncology-related HTAs were published in the study timeframe. Across studied nations, 38 (57%) decisions were favorable, 25 (37%) unfavorable, 1 (1%) mixed, and 3 (4%) neutral. Of those unfavorable decisions, 13 were rejected for insufficient benefit to justify the high cost (ie, improperly high incremental cost-effectiveness ratio [ICER]), 9 for insufficient or unproven clinical benefit vs the most appropriate comparator, and 3 for incomplete or improper submission. Excluding mixed and neutral decisions, France was associated with the highest percentage of favorable decisions (14 of 15; 93%), followed by Germany (9 of 14; 64%), Australia (11 of 20; 55%), and the UK (4 of 14; 29%). **CONCLUSIONS:** Based on the last 19 months of oncology-based HTAs, over 50% of decisions were favorable. The most significant factor leading to rejection for oncology products is the inability to prove cost-effectiveness vs the most appropriate comparator, followed by unproven clinical benefit. This analysis suggests that manufacturers would have more success with HTA decisions, particularly in the UK, if more robust health economic and clinical data are generated.

HT2
ASSESSING THE VALUE OF TREATMENTS FOR RARE DISEASES USING AN MCDA-BASED APPROACH: METHODOLOGICAL AND ETHICAL FOUNDATIONS OF CRITERIA SELECTION AND FRAMEWORK DEVELOPMENT

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BACKGROUND: Appraising rare disease treatments involves multiple issues and represents a significant challenge for HTA agencies. Multicriteria-approaches are uniquely suited to assess their real life value. **OBJECTIVES:** were to develop a framework adapted to rare diseases while remaining compatible with other therapeutic areas for broad application. **METHODS:** Adaptation of the framework to rare diseases was based on methodological and ethical principles underlying the EVIDEM framework, informed by issues and policies specific to rare diseases, which were identified through literature review and survey, and guided by pragmatic considerations of real life application in participatory processesCriteria selection followed MCDA principles: completeness; non-redundancy; operationalizability; and independence. MCDA model mechanics and sensitivity analyses were designed based on a review of MCDA modeling. **RESULTS:** Quantitative criteria of the framework are organized into a hierarchical MCDA model consisting of six domains of value (top-level criteria): *Need, Type of benefit, Outcomes, Economic consequences, Knowledge,* and *Established priorities*. Each domain includes criteria and subcriteria, each contributing to the final output of the model, i.e., the Value Estimate. The model explicitly takes into account aspects of rare diseases, including: disease complexity; treatment outcomes complexity; multiple economic and social consequences; data limitations and innovative approaches to tackle these; and health care system priorities. Weighting and scoring methodologies capture individual perspectives and judgments on the meaning of data while allowing for full exploration of uncertainty through six types of sensitivity analyses. Qualitative criteria support consideration of the impact of contextual issues. **CONCLUSIONS:** This framework promotes a comprehensive, transparent and systematic appraisal of rare disease treatments while remaining applicable to any therapy. Although numerical outputs are produced, the framework is intended to support deliberative processes that allow sharing of perspectives and rationales for decisions. Intended to measure value in its broad sense, the framework supports sustained application of MCDA in health care decisionmaking.

HT3
IDENTIFYING RECENT TRENDS IN HEALTH TECHNOLOGY ASSESSMENTS FOR CROHN'S DISEASE

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OBJECTIVES: To identify the types of coverage recommendations made by key ex-US health technology assessment (HTA) organizations for biologic treatments in Crohn's disease (CD) and to understand how these organizations interpret evidence to support these recommendations. **METHODS:** Publicly available HTAs on CD from January 2009 to June 2013 for the following organizations were reviewed: CADTH (Canada), CONITEC (Brazil), HAS (France), IQWiG (Germany), NICE (UK), PBAC (Australia), and ISCIII (Spain). HTAs were identified using an HTA search engine and were supplemented with separate manual searches for CD-related reports on each HTA organization's website. When additional context was needed to evaluate the HTA with the most recent recommendations, older HTAs were identified and reviewed. For each organization, the recommendation and corresponding clinical and economic rationales were reviewed and extracted. **RESULTS:** In total, nine HTAs were reviewed across five organizations; no HTAs on CD from IQWiG or ISCIII were identified. All HTAs endorsed the use of infliximab and adalimumab for CD from a clinical perspective. Recommendations for subpopulations including fistulizing disease, pediatrics, and prior/concurrent corticosteroid use varied. Recommendations were consistent with the host country's approved labeled indications when appropriate cost thresholds were met, with the exception of PBAC, where adalimumab was additionally deemed appropriate for fistulizing disease, and CONITEC, where certolizumab was not endorsed due to safety concerns. Research gaps identified include the lack of head-to-head trials for adalimumab vs. infliximab and the paucity of long-term clinical and economic evidence. **CONCLUSIONS:** Infliximab and adalimumab generally received positive endorsements in CD, despite being frequently scrutinized by HTA organizations for their high costs. The expiration of patents and the introduction of biosimilars will likely shift how HTA entities evaluate clinical, economic, and humanistic evidence for biologic treatments for CD in the future.

HT4
COST-EFFECTIVENESS REVIEWS BY HTA AGENCIES: A COMPARISON OF FACTORS LEADING TO UNFAVOURABLE REVIEWS FOR ONCOLOGY AGENTS

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OBJECTIVES: The purpose of this study was to identify factors leading to unfavourable reviews of cost-effectiveness analyses (CEAs) for oncology products by comparing recent summary reports from multiple HTA agencies. **METHODS:** We utilised reports issued by HTA agencies of the UK (NICE), Scotland (SMC), Canada (pCODR), and Australia (PBAC) for this study due to their detailed and publicly available evaluations of CEA submissions. We examined the factors driving unfavourable appraisals by comparing recent reports of 13 selected oncology drugs launched between January 2012 and December 2013. The following factors were examined and compared as predictors for negative decisions: (1) nature of the modelled patient population, (2) comparator selection, (3) survival analysis approach, and (4) sensitivity analyses performed. **RESULTS:** Issues related to one or more of these factors were often cited as leading to higher and more uncertain ICER values that HTA bodies viewed unfavourably. The SMC and NICE frequently took issue whether the patient populations sourced as inputs into the CEAs were representative of the intended indication in each respective country. All HTA agencies took issue with survival analysis methods that assumed a carry-over of benefit into post-treatment states. Similarly, HTA bodies typically critically examined the extrapolation methodology of studies with immature survival data. Although various combinations of these identified factors were likely to lead to negative HTA decisions, robust sensitivity analyses (especially regarding extrapolation methods and input sources) that clearly identified the factors driving ICER values were cited favourably by HTA agencies. **CONCLUSIONS:** Manufacturers must carefully select the survival analysis approach that is suitable for their asset given the clinical data available, such that the benefit of their product is not overstated; performing robust sensitivity analyses to account for uncertainty may help to maximise favourable HTA appraisal outcomes in CEA markets.

MEDICATION ADHERENCE STUDIES

MA1
NON-ADHERENCE IS ASSOCIATED WITH POORER HEALTH OUTCOMES AMONG WOMEN CURRENTLY TREATED FOR BREAST CANCER WITH ORAL ENDOCRINE THERAPY

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OBJECTIVES: Non-adherence rates with oral endocrine therapy (ET) in women with breast cancer (BC) are 25%-50% and lead to inferior survival. Understanding the effect of non-adherence on health outcomes is necessary to develop effective interventions. This study examined real-world non-adherence and health outcomes among women using ET. **METHODS:** Female respondents from the 2010-2012 U.S. National Health and Wellness Survey were included if reporting a diagnosis of BC and treatment with aromatase inhibitors (n=261), selective estrogen receptor modulators (n=113), or their combination (n=7). The Morisky Medication Adherence Scale (MMAS-4 or MMAS-8, modified for use in oncology) was used to assess adherence, standardized using z-scores. Descriptive analyses examined adherence, sociodemographics, and health behaviors. Bivariate analyses com-